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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/919,676	07/31/2001	Wilfred J. Samson	carde.58039	6658

7590 02/11/2004
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EXAMINER

THANH, LOAN H

ART UNIT PAPER NUMBER

3763

DATE MAILED: 02/11/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application N .

09/919,676

Applicant(s)

SAMSON ET AL.

Examiner

LoAn H. Thanh

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 November 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-28 is/are pending in the application.
- 4a) Of the above claim(s) 8, 16-20 and 22-26 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3, 5, 7, 9, 12, 21, 27 and 28 is/are rejected.
- 7) ☒ Claim(s) 4, 6, 10, 11 and 13-15 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 31 July 2001 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|----------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>5</u> . | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Election/Restrictions

Claims 16-20, 22-26 have been withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species A (figs. 1-9,12) , there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 4.

Claim 8 has been further withdrawn from consideration since it is drawn to a non-elected species .

An action on the merits now follows.

Information Disclosure Statement

The information disclosure statement filed 01/02/01 fails to comply with 37 CFR 1.98(a)(1), which requires a list of all patents, publications, or other information submitted for consideration by the Office. It has been placed in the application file, but the information referred to therein has not been considered. Applicant has failed to submit a proper listing of the references in a proper format for the Examiner to be consider.

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Drawings

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the at least one

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pressure valve (claim 4) in the porous section must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-3,5,7,9,12,27-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Machold et al. (U.S. Patent No. 5,611,775) in view of Boyd et al. (U.S. Patent NO. 5,558,644).

Machold et al. discloses a method of delivering fluid to the coronary arteries comprising the steps of providing an aortic catheter having a shaft , lumen and flow control member/ balloon having a porous section at the central region of the balloon to deliver therapeutic fluid/heart arresting fluid to the coronary ostia wherein the non-porous section substantially blocks fluid from passing therethrough. Machold further discloses the insertion of the catheter through the aorta and having the porous section proximate the coronary ostia and expanding the balloon with a fluid and delivering the fluid through the porous section. With respect to claim 5, lacking any distinguishing

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structural limitation of the porous window or strip, Machold is considered to show the porous window or strip in the broadest interpretation. See figures 1,4-6. columns 2-6. However, Machold et al. does not teach the aortic catheter to navigate by way through the **ascending** aorta. Boyd et al. disclose an aortic catheter that delivers therapeutic fluid/cardioplegic fluid to the coronary ostia or directly into the aortic root by navigating through the ascending aorta. Boyd et al. further teaches the delivery of fluid by infusing therapeutic fluid at a rate of at least 100ml/minute, preferably at least 200ml/minute. It would have been obvious to one of ordinary skill in the art to modify the delivery of the aortic catheter via the ascending aorta since it is well disclosed in the Boyd reference that the balloon catheter for arresting the heart can be inserted to provide antegrade or retrograde perfusion.

With respect to claim 27, Machold et al. teach flow rates. However, Machold does not teach the specifics of the initial flow rate or the reducing of the flow rates. Boyd et al. teaches different flow rates. Lacking any criticality in the flow rates, it would have been obvious to one of ordinary skill to modify the flow parameters as taught by Boyd et al. in order to provide sufficient therapeutic material according to dosing charts for different patients of different sizes and consideration of particulars of the disease or area to be treated which would be within the skill of one ordinary skill in the art.

Claims 1-3,5, 7, 9, 12, 21,28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Machold et al. (U.S. Patent No. 5,611,775) in view of Sweezer et al. (U.S. Patent NO. 5,478,309).

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Machold et al. disclose the invention as substantially claimed. See above. However, Machold does not disclose at least one perfusion port proximal the flow control member. Sweezer et al. disclose delivering cardioplegia fluid and perfusion ports proximal the balloon(s). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the catheter of Machold et al. with perfusion ports as taught by Sweezer et al. in order to provide a pathway for diversion of the fluid which is blocked.

Allowable Subject Matter

Claims 4, 6, 10-11,13-15 objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LoAn H. Thanh whose telephone number is (703) 305-0038. The examiner can normally be reached on Mon-Fri (first Friday off).


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on (703) 308-3552. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

LoAn H. Thanh
Primary Examiner
Art Unit 3763

LT



LOAN H. THANH
PRIMARY EXAMINER